SEP 1 1 2001

K011407

Siam Sempermed Corp., Ltd.
110 Moo 8 Kanjanavanit Rd., Hat Yai, Songkhla, Thailand 90230
Tel: 66 074 291 648 to 9 Fax: 66 074 291 650

510 (k) SUMMARY

12062001

1.0 APPLICANT:

Dr. POONSUK CHERDKIATGUMCHAI
SIAM SEMPERMED CORPORATION., Ltd.
110 MOO 8 KANJANAVANIT ROAD
PATHONG HATYAI SONGKHLA
THAILAND 90230
TEL: 66 074 291 648 OR 291 649
FAX: 66 074 291 650

2.0 CONTACT PERSON

Dr. POONSUK CHERDKIATGUMCHAI
SIAM SEMPERMED CORPORATION., Ltd.
110 MOO 8 KANJANAVANIT ROAD
PATHONG HATYAI SONGKHLA
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TEL: 66 074 291 648 OR 291 649
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MR WILLIAM HARRIS
SEMPERMED USA Inc.
30798 US Hwy. 19 N
Palm Harbor,
USA FL 34684
TEL: 727 787 7250
FAX: 727 787 7558

3.0 Device Class: I
Product code: 80LYY

4.0 Specification: Latex patient examination glove , Powder Free Glove , Blue color (Single side polymer coated
Class I 80LYY
meets all of the requirements of ASTM standard D3578-00

5.0 Device Description: Latex Patient Examination glove , Powder free Glove, Blue color (Single side polymer coated ,) , non sterile
50 micrograms or less of total water extractable protein per gram
Glove were tested for permeation with Chemotherapy Drugs

6.0 Intended use: A patient examination glove is a disposable device intended for medical purposes that is worn on the examiners hand or finger to prevent contamination between patient and examiner.

7.0 Surface treatment: Single side polymer coated , Halogenation / Siliconization and extensive washing in water.
Outer surface : Free from glove powder

8.0 Primary Dermal Irritation in Rabbits Guinea Pig Sensitization (Buehler) : Consumer Product Testing Co.
Experiment reference number : T98-0219 and T96-0153

Conclusion : According to Federal Hazardous Substances Act Regulation , (16 CFR 1500.41), and under the conditions of this test , This test article is not a primary dermal irritant
: This test article is not a sensitizer in guinea pigs, under condition of this test.

9.0 QUALITY CHARACTERISTICS

Dimensions	Meet ASTM D 3578-00

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Physical Properties	Meet ASTM D 3578-00
Protein content	50 micrograms or less of total water extractable protein per gram , according to ASTM D5712
Residue Powder	Meet ASTM D 3578-00
Freedom from pinholes	Meet ASTM D 3578-00 Meet ASTM D 5151

10. Conclusion: Siam Sempermed Latex patient examination glove , Powder Free Glove , Blue color (Single side polymer coated ,)

meet the ASTM standard or equivalent standard
meet pinhole FDA requirements
meet labeling claims (see 5.0 and 6.0 above)

Dr. POONSUK CHERDKIATGUMCHAI
Chief Quality Officer
12062001

P. Cherdkiatgumchai

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 11 2001

Ms. Katie Levinson
Product Manager
Sempermed USA, Incorporated
30798 US Highway 19 North
Palm Harbor, Florida 34684

Re: K011407
Trade/Device Name: Latex Powder-Free Examination Gloves Blue, Polymer Coated, Contains 50 Micrograms or Less of Total Water Extractable Protein Per Gram Test For Use with Chemotherapy Drugs
Regulation Number: 880.6250
Regulation Name: Patient Examination Gloves
Regulatory Class: I
Product Code: LYY
Dated: July 23, 2001
Received: June 26, 2001

Dear Ms. Levinson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

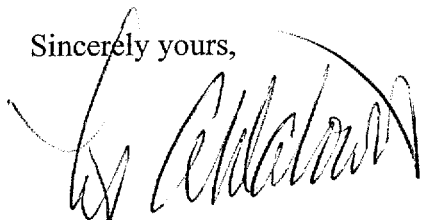
Please be advised that FDA's issuance of a substantial equivalence determination does not

mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (section 531-542 of the Act; 21); CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4618 . Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,



Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

Applicant: **Siam Sempermed Corp., Ltd.**

510(k) Number: **K011407**

Device Name: **Latex Patient Examination Glove Powder-Free (Blue Color, Polymer Coated, Tested for Use with Chemotherapy Drugs) containing 50 micrograms or less of total water extractable protein per gram.**

Indications for Use:

A patient examination glove is a disposable device intended for medical purposes that is worn on the examiners hand or finger to prevent contamination between patient and examiner.

Gloves to be used for protection against chemotherapy drug exposure during use with chemotherapy drug preparation and administration to patients. Chemotherapy drugs tested are: Vincristine Sulfate, Cyclophosphamide, Doxorubicin Hydrochloride, Paclitaxel, Cisplatin, and Etoposide.

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K011407